3.0 Registration

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REGULATED ACTIVITIES

The Animal Welfare Act (AWA) regulates the use of animals for research, tests, experiments and teaching. [1.1, Policy #10 & #16]

Registration

A USDA registration is required by any research facility engaging in regulated activities using covered animals, except when exempted by the Administrator by regulation.

Regulated activities include the following:

- the use or intent to use live regulated animals in:
 - research
 - tests
 - experiments
 - teaching
- the inoculation and selection of animals for the production of antibodies or antisera
- acquiring live animals for immediate euthanasia for tissue harvesting
- field studies that:
 - involve an invasive procedure
 - harm a live animal
 - ▶ materially alter an animal's behavior
- the surgical alteration of animals by a dealer as a necessary part of a proposed animal activity at a research facility.
 Note: Dealer must register as a research facility or the dealer's facility must be listed as a site of the research facility.
- genetically engineering regulated animals

NOTE: Certain regulated activities using cloned animals may require licensing. See page 3.1.2.

Licensed Exhibitors [Policy #10]

If a licensed exhibitor is conducting any of the following activities, he/she must also be registered as a research facility and meet all of the applicable standards and regulations:

- biomedical research (using animals as models for human applications)
- conducting invasive or painful/distressful procedures for

non-husbandry purposes

any research on domestic dogs and cats

Exemptions

The following activities are exempt from the registration requirement:

- research using only non-covered or non-regulated animals
- research using only dead animals or parts of dead animals
 [1.1]
- research on veterinary products for use only in agricultural animals [Policy #26]
- manufacturing of veterinary products for use only in agricultural animals [Policy #26]
- producing pregnant mare urine (PMU) [Policy #10]
- harvesting of normal blood or sera [Policy #10]
- collection of data by licensed exhibitors on animals with the intent of improving their nutrition, breeding, management or care. The methods used to collect data must: [Policy #10]
 - be performed as an adjunct to normal husbandry or veterinary procedures
 - ▶ be non-invasive
 - not cause pain or distress
 - not use domestic dogs or cats

Licensing

Research facilities, other than State universities or colleges, may require licensing as a dealer or broker if they:

- sell antibodies or antisera [Policy #10]
- sell regulated animals born at the research facility for regulated purposes
- wholesale regulated animals for regulated purposes
- clone animals which are to be utilized for regulated purposes
 [Policy #10]
- sell cloned animals for regulated purposes [Policy #10]

If you encounter one of these situations and have questions, contact your SACS.

REGULATED ANIMALS

Although all warm-blooded species are covered by the Animal Welfare Act, only certain animals are regulated under the Animal Welfare Act. [1.1, Policy #26]

Criteria

Regulated animals include, but are not limited to, live:

- dogs
- cats
- guinea pigs
- hamsters
- rabbits
- nonhuman primates
- marine mammals
- · wild or exotic animals
- farm animals used:
 - to test or produce biologicals for nonagricultural/ nonproduction animals. Biologicals include, but are not limited to:
 - vaccines
 - bacterins
 - toxoids
 - to test or produce biologicals for multiple species which includes a nonagricultural/nonproduction animal
 - for biomedical research
- equine species used for:
 - nonagricultural animal research
 - biomedical research

The species and activity involving the animal determines whether or not a USDA registration is required.

Exemptions

The following animals are exempt from the registration requirement:

- rats of the genus Rattus bred for use in research
- mice of the genus Mus bred for use in research
- birds bred for use in research
- domestic equine species used for the production of pregnant mare urine (PMU)

blood donor dogs used for client animal transfusions
NOTE: Dogs donating blood for use in a protocol are not
exempt and must be included in the protocol.

REGULATED FACILITIES

Certain facilities conducting research are regulated under the Animal Welfare Act. [1.1]

A facility conducting regulated research activities on regulated animals is required to be registered as a research facility.

A facility includes, but is not limited to:

- school (see exemptions below)
- institution
- organization
- person

Veterinary technician training programs must be registered if the facility:

- owns and houses regulated animals
- conducts regulated procedures or research on regulated animals, regardless of who owns or houses the animals

Note: See exemption criteria below.

Licensed exhibitors must be registered as a research facility and meet all of the applicable standards and regulations if they conduct any of the following activities:

- biomedical research (using animals as models for human applications)
- conducting invasive or painful/distressful procedures for non-husbandry purposes
- any research on domestic dogs and cats

Exemptions

The following facilities are exempt from the registration requirement:

- elementary schools [1.1]
- secondary schools [1.1]
- research facilities using only non-covered animals [1.1]
- Federal research facilities
 NOTE: Federal research facilities must establish an IACUC
 and comply with Section 2.31. However, the IACUC
 reports deficiencies to the head of the Federal agency. [2.37]

- veterinary technician training programs that meet the following criteria:
 - all the regulated animals used are client-owned (private citizen or shelter/pound)
 - the procedures are accepted veterinary or husbandry practices
 - the students are under the supervision of a licensed veterinarian
 - ▶ there is a valid veterinarian-client-patient relationship

A facility conducting research on a minimal number of animals other than dogs and cats may request an exemption from the registration requirement. The exemption request must:

- be in writing
- contain the details of the protocol
- justify why an exemption should be granted
- explain how the design of the protocol meets the intent of the AWA
- contain information on the facility's past and possibly future research activities
- give the name of any Federal funding source, if applicable
- be sent to the appropriate Animal Care Regional Office

OBTAINING A NEW REGISTRATION

All facilities engaging in research activities covered by the AWA must have a valid registration. [2.30]

Criteria

The research facility must:

- submit a properly completed APHIS Form 7011 (Application for Registration) (see 3.4.4)
- have the Institutional Official or CEO sign APHIS
 Form 7011:
 - certifying that the information provided is true and correct
 - acknowledging receipt of the regulations and agreeing to comply with the regulations and standards
- complete and submit the Taxpayer Identification
 Number (TIN) sheet (see 3.4.5)
- submit the completed Application and TIN sheet to the Animal Care Regional Office for the State in which the principal place of business/headquarters is located

Registering Unit

The registering unit is the lowest independent legal entity which uses or intends to use live animals for research, tests, experiments, or teaching.

College or University School or Department:

The college or university is considered the research facility, rather than the school or department, UNLESS the school or department demonstrates to the AC Deputy Administrator that:

- it is a separate legal entity, and
- its operations and administration are independent of the college or university

Business Corporation

The subsidiary of a business corporation is considered the research facility, rather than parent corporation, UNLESS:

- the subsidiary is under direct control of the parent corporation, and
- the AC Deputy Administrator determines that, based on

this control, the parent corporation is the unit to be registered

Federal Research Facility

A Federal Research Facility is exempt from registration by the USDA.

Registrant

Registrant must provide all of the following information on the Application for Registration:

- name of the research facility
- valid mailing address
- a list of all locations where animals are housed, used or regulated activities occur
- business information requested on APHIS Form 7011
- name, title and address of each partner or principal officer

Note: It is strongly recommended that a contact person and phone number be submitted with the Application for Registration.

Issuance of a Registration

Registrations are issued to a specific research facility.

If a non-registered institution, organization or person acquires or purchases a registered research facility, the new owner must, before conducting any regulated activities:

- properly complete an Application for Registration
- file the Application with the appropriate AC Regional Director

If two or more registered research facilities merge, and:

- a completely new research facility is formed, the new research facility must:
 - inform the appropriate AC Regional Office
 - in writing
 - by certified mail
 - within 10 days of the change
 - have the merged research facilities cancel their registrations

- complete a new Application for Registration
 one registered research facility absorbs the other one(s),
 the research facility must:
 - ▶ inform the appropriate AC Regional Office
 - in writing
 - by certified mail
 - within 10 days of the change
 - have the absorbed research facility(s) cancel its registration
 - submit a list of the absorbed research facility's sites or locations which are to be added to the existing registration
 - complete a new Application for Registration
 (APHIS Form 7011) ONLY if the Institutional
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IMPORTANT

THE FEDERAL DEBT COLLECTION ACT of 1996 requires us to obtain your Taxpayer Identification Number. This would be either your <u>Social Security Number</u> or your <u>Employer</u> <u>Identification Number</u>.

This number is for the purpose of collecting and reporting on any delinquent amounts arising out of a person's relationship with the government.

Our computer system will no longer allow processing of your license renewal without entering on of the above numbers.

We appreciate your cooperation in this matter. Please complete the following blanks and return this with your renewal application.

Your Name	
License/Registration #:	
Social Security Number:	
	OR
Employer Identification Number: _	

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COMPLIANCE WITH STANDARDS	Each research facility must comply with the regulations set forth in Part 2 and with the standards set forth in Part 3 of Subchapter A-Animal Welfare. [2.30(b), 2.38(k)]			
	By signing the APHIS Form 7011 (Application for Registration), the Institutional Official on behalf of the research facility agrees to comply with the regulations and standards for the: use handling care treatment housing, and transportation of animals			
Exemptions/ Exceptions	A research facility may make exemptions or exceptions to the regulations in subpart C of Part 2 and the standards in Part 3 when the exemptions/exceptions are: [2.38(k)] specified in the animal activity proposal justified in the proposal approved by the IACUC approved by the APHIS Administrator			

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REGISTRATION UPDATE

A research facility must submit an update of its registration on or before the expiration date listed on the registration certificate. [2.30(a)]

Criteria

Registration updates are:

- sent to the research facility at least 60 days prior to the expiration date of the registration
- submitted by the research facility to the AC Regional Office for the State in which the principal place of business/headquarters is located

The research facility must submit the properly completed APHIS Form 7011 (Application for Registration), signed by the Institutional Official:

- certifying that the information on the form is true and
- · acknowledging receipt of the regulations and standards
- agreeing to comply with regulations and standards

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DURATION OF A REGISTRATION	A registration is issued for three years. [2.30(a)]				
	A registration is issued for three years and must be updated triennially.				
	A registration shall be valid and effective unless it is voluntarily terminated upon written request of the research facility. Note: The Voluntary Cancellation of License/Registration sheet may be used (see page 3.7.2).				
	If a registration has been terminated, the research facility must apply for a new registration to conduct regulated activities.				

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VOLUNTARY CANCELLATION OF LICENSE/REGISTRATION

TO: United States Department of Agriculture Animal and Plant Health Inspection Service Animal Care I wish to cancel my license/registration as a USDA licensed or registered Carrier Intermediate Handler Exhibitor Research **Facility** LICENSE/REGISTRATION NUMBER _____ NAME ADDRESS CITY, STATE, ZIP CODE _____ TELEPHONE NUMBER __(____) I am discontinuing operations as a dealer, exhibitor, research facility, carrier, or intermediate handler and do voluntarily surrender my license/registration. I understand that if a license or registration is required in the future, it will be necessary to apply for a license/registration and meet all the requirements. Furthermore, I understand that operating without a license/registration is a violation of the Animal Welfare Act and subject to punishment. MY LICENSE/REGISTRATION CERTIFICATE IS ATTACHED. I CANNOT RETURN MY LICENSE/REGISTRATION CERTIFICATE BECAUSE: DATE SIGNATURE PRINT NAME

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SITES

A registered research facility may have one or more sites where it conducts regulated activities.

Definitions

Site: All locations within a 35-mile radius of the research facility's headquarters where regulated animals are housed or used in research.

Location: A group of housing facilities/research areas on the same premises.

Housing facility: Any land, building, barn, shed, trailer, or other structure or area, housing or intended to house regulated animals.

Research area: Any land, building, barn, shed, trailer, or other structure or room where research, tests, experiments, or teaching is conducted or intended to be conducted on regulated animals.

Exception to the definition of a site:

If the use of the definition of site causes a major problem at a research facility, consider the following factors and discuss the situation with your supervisor:

- locations in another State, county, city, or town and less than 35 miles from the research facility's headquarters
- a distance of less than 35 miles where travel time between locations is a major factor
- organizational structure of the research facility, such as:
 - reporting lines of authority
 - budget allocations
 - operations and administrative control
- records repository at a location where no animals are housed

NOTE: Time necessary to inspect all housing facilities at a site is not sufficient for an exception to the definition.

Reporting of Sites

The research facility must list all locations where animals are housed, used, or held, on the Application For Registration (APHIS Form 7011) and the Annual Report of Research Facility (APHIS Form 7023).

Consolidation of Sites

For consistency throughout the country, existing sites are to be consolidated to meet the new definition of a site.

The inspector may consolidate sites by:

- completing a Request to Add/Delete Sites sheet (see page 3.8.4):
 - identifying all sites that are being incorporated into an existing or new site number as sites to be "deleted"
 - identifying any new sites as sites to be "added"
 - obtaining the signature of the research facility representative
- sending the add/delete site sheet to the Regional Office
- documenting the following on the inspection report:
 - the name of all locations within a site that were inspected
 - all previous sites that are being incorporated into an existing or new site number

Addition of a Site

A research facility may add a site to its registration by submitting to the appropriate Animal Care Regional Office, one of the following:

- a letter of notification
- the Request to Add/Delete Site sheet (see page 3.8.4)
- an amended Application for Registration (APHIS Form 7011)

The Regional Office will inform the field inspector of the addition of the new site.

Note: A new research facility site does **not** have to be inspected prior to its being used to house animals or conduct research.

Deletion of a Site

A research facility may delete a site from its registration by submitting to the appropriate Animal Care Regional Office, one of the following:

- a letter of notification
- the Request to Add/Delete Site sheet (see page 3.8.4)

The Regional Office will inform the field inspector of the deletion of the site.

Change of Headquarters Site

Within the same State:

If the research facility moves its headquarters to another site or to another location within a site:

- the research facility must notify the appropriate Animal Care Regional Office:
 - in writing
 - by certified mail
 - within 10 days of the move

To a different State:

If the research facility moves its headquarters to another State or territory of the U.S., the research facility must:

- notify the appropriate Animal Care Regional Office:
 - in writing
 - by certified mail
 - within 10 days of the move
- complete a new Application for Registration (APHIS Form 7011), and
- submit the new Application to the appropriate AC Regional Office

The Regional Office will inform the field inspector of the headquarters site change.

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REQUEST TO ADD/DELETE SITES

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NOTIFICATION OF CHANGE OF OPERATION

A research facility must notify the appropriate Animal Care Regional Office of any change of operation. [2.30]

Criteria

Changes in operation include, but are not limited to:

- a change of: [2.30(c)(1)]
 - ▶ name
 - address
 - ownership (see below)
 - headquarters site (see page 3.9.2)
- any change affecting status as a research facility, such as:
 - no longer conducting research
 - no longer using regulated species

The AC Regional Office must be notified: [2.30(c)(1)]

- by certified mail
- within 10 days of the change

The Regional Office will inform the field inspector of any change in a research facility's operation.

Change of Ownership

If a non-registered institution, organization or person acquires or purchases a registered research facility, the **new owner** must, before conducting any regulated activities:

- properly complete an Application for Registration (APHIS Form 7011)
- file the Application with the appropriate AC Regional Director

The previous owner of the registered research facility must:

- inform the appropriate Animal Care Regional Office of the sale or disposition
- in writing
- by certified mail
- within 10 days of the change

If two or more registered research facilities merge, and:

- a completely new research facility is formed, the new research facility must:
 - ▶ inform the appropriate AC Regional Office
 - in writing
 - by certified mail
 - within 10 days of the change
 - have the merged research facilities cancel their registrations
 - complete a new Application for Registration
- one registered research facility absorbs the other one(s), the research facility must:
 - ▶ inform the appropriate AC Regional Office
 - in writing
 - by certified mail
 - within 10 days of the change
 - have the absorbed research facility(s) cancel its registration
 - submit a list of the absorbed research facility's sites or locations which are to be added to the existing registration
 - complete a new Application for Registration (APHIS Form 7011) ONLY if the Institutional Official, partners, or principal officers change

Change of Headquarters Site

Within the same State:

If the research facility moves its headquarters to another site or to another location within a site:

- the research facility must notify the appropriate Animal Care Regional Office:
 - in writing
 - by certified mail
 - within 10 days of the move

To a different State:

If the research facility moves its headquarters to another State or territory of the U.S., the research facility must:

- notify the appropriate Animal Care Regional Office:
 - in writing

- by certified mail
- within 10 days of the move
- complete a new Application for Registration (APHIS Form 7011), and
- submit the new Application to the Animal Care Regional Office

Inactive Status

A research facility may request being placed in an inactive status, if for at least 2 years, it has **not**: [2.30(c)(2)]

- used, or
- handled, or
- transported regulated animals

The inactivation request must be:

- in writing
- submitted to the appropriate AC Regional Office [2.30(c)(2)]

After inactivation, the research facility must: [2.30(c)(2)]

- file an annual report of its status, i.e., inactive or active
- notify the appropriate AC Regional Office at least 10 days prior to restarting any regulated research activities

NOTE: An inactive research facility should be inspected at least once a year (see Section 8.5).

Cancellation

A research facility may cancel its registration, if it: [2.30(c)(3)]

- goes out of business, or
- ceases to function as a research facility, and
- does not plan to:
 - ▶ use, or
 - handle, or
 - transport regulated animals

The cancellation request must: [2.30(c)(3)]

- be in writing (Voluntary Cancellation of License/ Registration sheet may be used-see page 5.4.37)
- be submitted to the appropriate AC Regional Office

The research facility must obtain a new registration if it starts conducting covered activities after its registration has been canceled. [2.30(c)(3)]